

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA VA 22313-1404

COPY MAILED

OCT 0 1 2009

OFFICE OF PETITIONS

In re Patent No. 7,498,492

Issued: March 3, 2009 Application No. 10/003,405 Filed: December 6, 2001

Attorney Docket No. 1021565-000110

: DECISION ON APPLICATION : FOR PATENT TERM ADJUSTMENT

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT PURSUANT TO 37 C.F.R. 1.705(d)" filed May 2, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from Five Hundred Twenty Six (526) days to Nine Hundred Thirty-Eight (938) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On March 3, 2009, the above-identified application matured into US Patent No. 7,498,492 with a patent term adjustment of 526 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required. The Office notes that applicant informally requested suspension of the proceeding until resolution of the Wyeth disposition. The Office notes that it is not suspending decisions on the 37 CFR 1.705(d) requests for PTA reconsiderations because suspension of the rendering of decisions on requests for reconsideration of the determination of patent term adjustment under 37 CFR 1.705(d) presently before deciding Officials is inconsistent with the statutory framework, 35 U.S.C. 154, which only allows 180 days for filing a civil action challenging the Office's decision.

<sup>&</sup>lt;sup>1</sup>It is noted that such request was not pursuant to 37 CFR 1.182 or 1.183. However, in the interest of providing a response to applicant, the Office is outlining its position as to suspension of decision per outcome of CAFC decision.

Patentees request recalculation of the patent term adjustment based on the decision in <u>Wyeth v. Dudas</u>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that in view of the decision in <u>Wyeth</u>, they are entitled to a total patent term adjustment of 938 days, which is the sum of 1037 days of patent term adjustment due to exceeding three year pendency and 412 days due to USPTO delay in prosecution minus 511 days of applicant delay.

The 1037-day period is calculated based on the application having been filed under 35 U.S.C. 111(a) on December 6, 2001, and a request for continued examination (RCE) having being filed on October 9, 2007. The filing of an RCE cuts-off the applicants' ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment. 37 CFR § 1.703(b)(1). Patentees assert that in addition to this 1037-day period, they are entitled to a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a), of 412 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a), pursuant to 37 CFR 1.702(a)(1).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, it is the period of Office delay reduced by the period of applicant delay. Patentees do not dispute the period of reduction of 511 days for applicant delay.

Patentees do not dispute that the total period of Office delay is the sum of the period of Three Years Delay (1037 days) and the period of Examination Delay (412 days) to the extent that these periods of delay are not overlapping. However, in effect, patentees contend that no portion of the Three Year Delay period overlaps with the period of 14-month examination delay. Accordingly, patentees submit that the total period of adjustment for Office delay is 1449 days, which is the sum of the period of Three Year Delay (1037 days) and the period of Examination Delay (412 days), reduced by the period of overlap (0 days). As such, patentees assert entitlement to a patent term adjustment of 938 days (1037 + 412 reduced by 0 overlap – 511(applicant delay)).

The Office agrees that as of the filing of the RCE on October 9, 2007, the application was pending three years and 1037 days after its filing date. The Office agrees that the action detailed above was not taken within the specified time frame, and thus, the entry of a period of adjustment of 412 days is correct. At issue is whether patentees should accrue 1037 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 412 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 1037 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely

track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f)* and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>2</sup>

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

In this instance, the relevant period under 35 U.S.C. 154(b) (I) (B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b) (2) (A) is the entire period during which the application was pending before the Office until the filing of the RCE. December 6, 2001 to October 9, 2007. During that time, the issuance of the patent was delayed by 1037 days, not 412 + 1037 days. The Office took 14 months and 412 days to issue a first Office action. Otherwise, the Office took all actions set forth in 37 C.F.R. § 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 412 days of Office delay and the 511 days of applicant delay and the time allowed within the timeframes for processing and examination, at the time of filing of the RCE, the application was pending three years and 1037 days after its filing date. The Office did not delay 412 days and then an additional 1037 days. Accordingly, 1037 days of patent term adjustment (not 412 and 1037 days) was properly entered since the period of delay of 1037 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 412 days attributable to grounds specified in § 1.702(a)(1). Entry of both periods is not warranted. 412 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 1037 days over three years.

Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment for the Office taking in excess of three years to issue the patent.

In view thereof, no adjustment to the patent term will be made.

Telephone inquiries specific to this decision should be directed to Senior Petitions Attorney Patricia Faison-Ball at (571) 272-3212.

/Kery A. Fries/

Kery A. Fries Senior Legal Advisor Office of Patent Legal Administration Office of Deputy Commissioner for Examination Policy